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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,016	02/28/2007	Mads Hald Andersen	ANDERSEN8	7719

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EXAMINER	
YU, MISOOK	
ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
01/20/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,016	ANDERSEN ET AL.	
	Examiner	Art Unit	
	MISOOK YU	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52,54-75 and 81-83* is/are pending in the application.

4a) Of the above claim(s) *8,9,13,14,24-30,50,51,54-57,66-75 and 81-85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-13,16-23,31-49,52 and 58-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/1/09,5/15/08,3/12/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group 1 with species SEQ ID NO: 8 (Bcl-2 epitope) as peptide and HLA-A2 as the MCH molecule in the reply filed on 11/03/2009 is acknowledged. The traversal is on the ground(s) that group VIII drawn to using the product should be examined under PCT Rule 13.1. This is not found persuasive because the method of using the product would have unity of invention if only the product contributes over the art. Since the first claimed product is anticipated by the cited art (note the copy provided with ISR), the first claimed product does not contribute over the art, thus unity of the invention is lacking, and the method of using the previously known product is not included with the elected product.

The requirement is still deemed proper and is therefore made FINAL.

Claims 50, 51, 54-57, 66-75 and 81-85 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 8 and 14 drawn to Bcl-XL (not the elected Bcl-2) and claims 9 and 15 drawn to Mcl-1 (not Bcl-2), claims 24-30 drawn to other HLAs are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 1-52, 54-75 and 81-83 are pending. Claims 1-7, 10-13, 16-23, 31-49, 52 and 58-65 are examined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 10-13, 16-21, 31-47, and 61-65 are rejected under 35 U.S.C. 102(a) as being anticipated by Akatuska et al., IDS filed on 03/12/2007, J. Exp. Med. June 2, 2003, Vol. 197, pages 1489-1500.

Claims 1-6, 10-13, 16-21, 31-47, and 61-65 are broadly drawn to a T-cell antigen from Bcl-2 protein family or for use as an vaccine.

Akatuska et al., on page 1494 teaches two HLA-A restricted epitopes from Bcl-2 protein family (i.e. Bcl-2A1).

For art searching purpose, the intended use in vaccine does not differentiate the claimed composition away from the composition of the prior art because the claims read on the composition per se, which is a T-cell epitope from Bcl-2 family.

Since the structure of the prior art is same as the claimed structure, the structure of the prior art must have the same function.

Claims 1-4, 6, 10, 12, 31-37, and 61-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Saeterdal I., et al, PNAS, 2001 Nov 6;98(23):13255-60, IDS filed on 03/12/2007

Claims 1-4, 6, 10, 12, 31-37, and 61-65 are broadly drawn to a peptides from Bcl-2 family.

Saeterdal I. et al., teach on page 13255, left column under the heading "Peptides" teaches several Bax peptides.

For art searching purpose, the intended use in vaccine does not differentiate the claimed composition away from the composition of the prior art because the claims read on the composition per se, which is a T-cell epitope from Bcl-2 family.

Since the structure of the prior art is same as the claimed structure, the structure of the prior art must have the same function.

Claims 1-7, 10-13, 16, 23, 34-37, and 61-65 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5789201 (08-1998).

US Patent No. 5789201 teaches a 21 amino acids peptides that are 100% identical to the elected species of the instant SEQ ID NO: 8. Note the sequence alignment below:

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US-08-798-897-13

  Query Match             100.0%;  Score 56;  DB 1;  Length 21;
  Best Local Similarity   100.0%;
  Matches   10;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy          1 PLFDFSWLSL 10
              ||||||||||
Db          4 PLFDFSWLSL 13
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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 10-13, 16-23, 31-47, 52 and 61-65 are examined rejected under 35 U.S.C. 103(a) as being unpatentable over Saeterdal I. et al., (cited above) in view of Akatuska et al., (cited above) .

The claimed invention is broadly drawn to a T-cell epitope from Bcl-2 family protein wherein the T cell epitope is restricted by HLA-A2 (elected species) in claim 22, and the T cell epitope is used in vaccine and has the various characteristics specified in the dependent claims.

Saeterdal I. et al., teaches that BAX is a cancer related gene (note 2nd paragraph on page 13255) and also teaches several peptides derived from BAX, which was used to stimulate T cells from patients and normal donors. Saeterdal I. et al., teaches one of

ordinary skill in the art knows how to select HIA-A2-restricted CTL epitope (note left column on page 13260).

Saeterdal I. et al., teaches one reason for the tested BAX peptide not showing the T-cell specific memory response is the number of patients tested (note page 13260, right column).

However, Akatuska et al., et al., teach T-cell epitopes from Bcl-2 family protein showing a strong T cell response and also teaches that these peptides could be sued for immunotherapy for various types of recurrent malignancies after allogeneic HCT.

Therefore it would have been obvious to one of ordinary skill in the art to arrive at the broadly claimed T cell epitopes from any Bcl-2 protein with a reasonable expectation of success since Akatuska et al., teaches Bcl-2 protein family could be used in immunotherapy (vaccine).

One of ordinary skill in the art would have been motivated to arrive at claimed invention by increasing patient's numbers, especially including patient having HLA-2 since Saeterdal I., teaches that one possible reason for lack of T-cell response is the limited number of patients tested.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MISOOK YU
Primary Examiner
Art Unit 1642

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